



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,414	07/10/2003	Ben C. Askew	20610YDA	6800
210	7590	11/23/2005	EXAMINER	
MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907			TRUONG, TAMTHOM NGO	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/618,414

Applicant(s)

ASKEW ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 7-10-03 (Preliminary Amendment).
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-7 and 9-24 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

Art Unit: 1624

Applicant's preliminary amendment of 7-10-03 is acknowledged and entered. Claim 8 is cancelled. Claims 1-7 and 9-24 are pending.

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Group 1: Claims 1-7 and 9 (in part), drawn to compounds of formula (I) wherein X is **pyrimidinyl** or **tetrahydropyrimidinyl**, and pharmaceutical composition thereof, classified in class 514, subclass 269, and class 544, subclass 333.
- Group 2: Claims 1 and 9 (in part), drawn to compounds of formula (I) wherein X is **1H-pyrrolo [2,3-b]pyridine**, and pharmaceutical composition thereof, classified in class 514, subclass 300, and class 546, subclass 113.
- Group 3: Claims 1 and 9 (in part), drawn to compounds of formula (I) wherein X is **2H-pyrido[3,2-b]-1,4-oxazine**, and pharmaceutical composition thereof, classified in class 514, subclass 234.5, and class 544, subclass 105.
- Group 4: Claims 1 and 9 (in part), drawn to compounds of formula (I) wherein X is **pyrido[2,3-b]-tetrahydro-pyrazine**, and pharmaceutical composition thereof, classified in class 514, subclass 250, and class 544, subclass 350.
- Group 5: Claims 1 and 9 (in part), drawn to compounds of formula (I) wherein X is **pyrido[2,3-b]-azepine**, and pharmaceutical composition thereof, classified in class 514, subclasses 212.07, 215, and class 540, subclass 523.

Group 6: Claims 10-12, drawn to a pharmaceutical composition comprising compounds of formula (I) and an additional active ingredients, classified in class 514, 540, 544, 546, etc., various subclasses. Further restriction and election of species will be required if this group is elected.

Group 7: Claims 13-24, drawn to various methods of treatment and prevention as well as method of antagonizing  $\alpha\beta 3$  receptor, and antagonizing dual  $\alpha\beta 3/\alpha\beta 5$  using compounds of formula (I) and an additional active ingredients, classified in class 514, 540, 544, 546, etc., various subclasses. Further restriction and election of species will be required if this group is elected.

Inventions of Groups 1- 7 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are distinct by the various rings represented by X, and composition with additional active ingredient as well as various methods of use.

The inventions of groups 1-5 are drawn to compounds having a common core of –  
 $\text{CH}_2\text{CO}_2^-$ . Such a core does not sufficiently define the invention, or contribute to the art. It is the ring represented by X that gives the compounds of Groups 1-5 their unique physical, chemical properties as well as biological activities. Therefore, a reference that anticipated or rendered obvious compounds of one group would not do so to those of other groups. Thus, a separate search is required for each group.

The invention of Group 6 is drawn to a pharmaceutical composition of compounds of formula I and additional active ingredient(s), which requires additional search. Likewise, the invention of Group 7 also needs additional search since a reference reading on the compounds, might not teach the same biological activity, treatment or prevention. Thus, the search and examination of all 7 groups would impose a serious burden on the examiner. Furthermore, a preliminary search in EAST yields a total of 7,793 hits which clearly shows an overwhelming number of references for consideration.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their divergent subject matter, and to search as well as examining the 7 distinct inventions would indeed impose a serious burden on the examiner in charge of this invention, restriction for examination purposes as indicated is proper.

Due to the complexity of the grouping, the restriction is presented in writing. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn method claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method claims will be withdrawn, and the rejoined method claims **will be fully examined for patentability in accordance with 37 CFR 1.104**. Thus, to be allowable, the **rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112**. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and method claims may be maintained. Withdrawn method claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so**

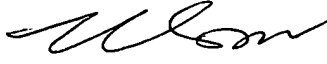
Art Unit: 1624

**may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

-----  
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (9:30-6:00).

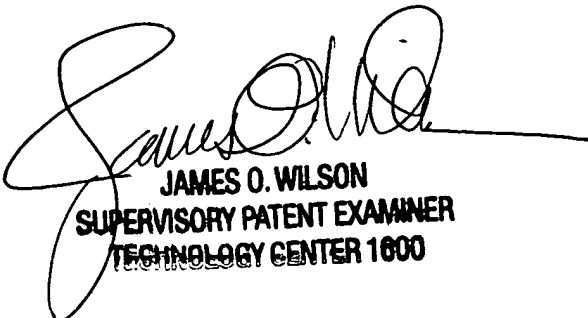
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**Tamthom N. Truong**  
**Examiner**  
**Art Unit 1624**

\*\*\*

11-16-05

  
**JAMES O. WILSON**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**